# ESSENTIAL HAND SANITIZER- alcohol liquid reX Solutions LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

## Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

## Purpose

Antiseptic, Hand Sanitizer

#### Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

## Warnings

For external use only. Flammable. Keep away from heat or flame

#### Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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away.

#### Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing. •

#### Other information

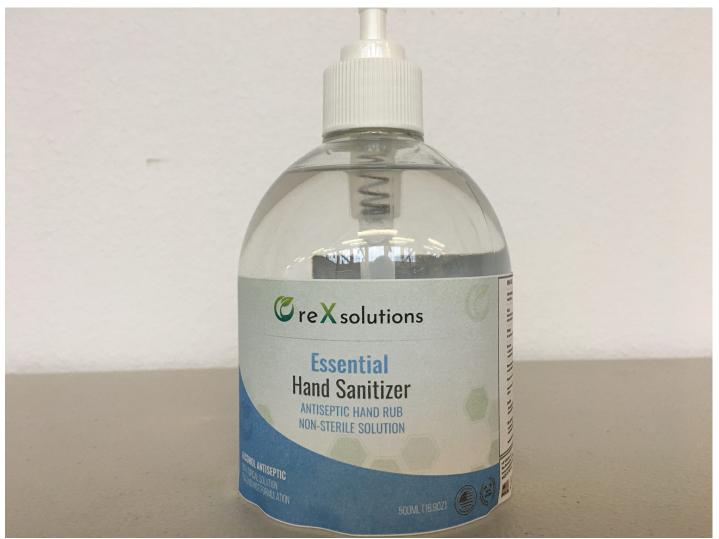
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F) •

## **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

### Package Label - Principal Display Panel

500 mL NDC: 77853-000-01



## **ESSENTIAL HAND SANITIZER**

alcohol liquid

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Product Type		HUMAN OTC DRUG	m Code	e (Source	) 1	NDC:77853-000	
Route of Administration	n	TOPICAL					
Active Ingredient/A	ctive Moi	ety					
Ingredient Name					of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)					L	80 mL in 100 mL	
Inactive Ingredients	5						
Ingredient Name					Strength		
GLYCERIN (UNII: PDC6A3C0OX)					1.45 mL in 100 mL		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)				0.125 mL in 100 mL			
WATER (UNII: 059QF0K00R)							
Packaging							
00		Package Description	N	<i>f</i> arke ting	g Start Date	Marketing End Date	
		<b>Package Description</b> ITLE; Type 0: Not a Combination Pr			-	Marketing End Date	
# Item Code		<b>•</b> •			-	Marketing End Dat	
# Item Code		<b>•</b> •			-	Marketing End Dat	
# Item Code	0 mL in 1 BO'	<b>•</b> •			-	Marketing End Dat	
# Item Code   1 NDC:77853-000-01 500	0 mL in 1 BO' <b>mation</b>	<b>•</b> •	oduct 0	3/30/2020	-	Marketing End Date Marketing End Date	

Labeler - reX Solutions LLC (117513438)

Establishment								
Name	Address	ID/FEI	Business Operations					
reX Solutions LLC		117513438	manufacture(77853-000)					

Revised: 6/2020

reX Solutions LLC